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In this episode, Taren Grom, editor-in-chief of PharmaVOICE magazine, meets with Joanne Quan, M.D., chief medical officer of Modis Therapeutics, a Zogenix company.

Taren: Dr. Quan, welcome to the WoW podcast program. It's a delight to meet you.

Dr. Quan: Great to talk to you, Taren. Appreciate your inviting me.

Taren: Tell me about the beginning of your career and how it led to your current position in the C-suite.

Dr. Quan: Well, when I was an undergraduate and in medical school, I was always interested in research and I thought I was going to go into academics. So I had done lab research when I was an undergraduate at UC Berkeley when I was a medical student at Stanford, and then as part of my fellowship training in Seattle at University of Washington in pulmonary and critical care. I was really always interested in thinking about scientific problems and really how to solve them. When I was in Seattle, I had the good fortune to collaborate with a local biotech company. My research advisor had set up a collaboration and I was to go to the local biotech company and learn some techniques and bring them back to our lab which is at the VA hospital. So I actually spent some time working at the bench alongside a number of people in the biotech industry.

At that time, if you were in academics, there really was a bias against the industry. There was a sense that because this was a business, the novel motives were kind of sullied by that commercial setting. But what I really saw was that there was really good science that was being done in an industry setting and it was a very rigorously done science, and it really opened my eyes to looking at both industry and academic positions when it came time about me taking the next step. Back then, there really were not many physicians who went into industry especially those on the West Coast. I think it was a bit more common on the East Coast because there were established companies, everyone's heard of Merck. On the West Coast, there were smaller startup companies and really the census was a lot riskier, and you may be familiar physicians are not usually risky people kind of as a group.

So I had talked to as many people as I could about it. There was one other person in my program who had gone to industry but very few, and really at the time it felt like a bit like jumping off a cliff. But there were a few things that really attracted me, one of the things that I realized is I like thinking in the future and I really liked the idea that you could really crystallize a lot of clinical medicine and scientific knowledge into developing something as concrete as a drug. So really taking a lot of ideas and abstract concepts and then bringing it to something

concrete that could help a lot of people. It's really different than how I started thinking of a role of a physician where you affect people one by one, but I realized that you could have a huge impact by developing a drug that can affect lots of people at the same time.

And so I ended up joining a small company in Seattle and had a major role in bringing a new medicine for cystic fibrosis to the market. This was inhaled tobramycin or called TOBI and this all really occurred within a couple of years of my joining industry. It was actually a great experience, and at that point I realized that I'd made the right decision even though really only a couple of years before it felt like a big leap of faith at that point. And since then, I've been part of smaller companies and larger companies and really gravitated to smaller companies, smaller medium-sized companies, and working on rare diseases.

Taren: And why is that particular focus? Obviously, working on that CF drug was pretty revolutionary because there hadn't been anything new in that field for quite some time so that had to be terribly exciting. But why they interest in small to medium-sized rather than the larger pharma companies? What is it about those that attracted you?

Dr. Quan: Yeah. What I find is that small companies, it's much more straightforward to have something innovative and have it go forward in a small company. And so you have to get a certain group of people on board to move a project forward. Often, in a larger company, you have to get a much larger group of people on board. There's a certain nimbleness as well in terms of a small company and being able to kind of turn the ship quickly and react to changes. And I really liked that combination of kind of having the right expertise within the company within a small group of people, and then being able to adapt whether it's to something that you're finding in terms of your clinical trial or the drug that you're developing, a new scientific area, or something that's outside a competitor or other challenges like that. So there's a real sort of immediacy and kind of nimbleness to the environment which I find really compelling.

Taren: Excellent. It appeals to that kind of entrepreneurial spirit that you have inside you because it is so fast moving that you have to kind of be able to pivot very quickly and nimbly.

Dr. Quan: Yeah, exactly.

Taren: And what about the rare disease space? What is it that attracts you about that area of focus? Because as a physician, you could have gone into any area I would think.

Dr. Quan: Right. Well, as I said, I started working out in rare diseases that really wasn't my intent, that realism wasn't by design. It was because there was an opportunity and as I was trained in pulmonary medicine, cystic fibrosis was familiar to me. So that was a bit happenstance. As it turns out, there's a number of things that really resonate with me about rare diseases. There's a very high unmet need and that sort of kind of tracks with my training as a critical care physician and really wanting to take care and kind of respond to people who are very ill. There's a need for novel approaches and creativity to developing treatments for diseases, some of which may not be very well understood and for which there are typically no or very few precedents to guide you.

I also find that physicians and caregivers for patients who have rare diseases are very special. It takes a tremendous commitment to care for patients with rare conditions who may be very ill, who may require very complex medical care, and they're always kind of on the edge in terms of what the medical knowledge is and I like this shared commitment within that community. I've also found that in rare diseases, I have the ability to interact with a lot of different people, physicians, patients, advocates, caregivers, and really appreciate kind of end-to-end the aspects of disease and there's a certain immediacy to this that I really like.

At Zogenix, I'm currently working on a rare disease called thymidine kinase 2 deficiency or TK2 for short and this is a very rare mitochondrial disease. You may remember mitochondria as the powerhouse of the cell, so patients with mitochondrial disease may have really very severe fatigue and progressive muscle weakness. So they may have difficulty walking, rising from a chair, climbing stairs, eating, breathing because all of the muscles are affected. And something that we take for granted like eating a meal for instance can be incredibly tiring for people with mitochondrial diseases.

And so I'm able to appreciate not just the science about the disease but I can appreciate talking to different patients who have the disease, talking to their families, understanding how the disease affects them, and as well how development treatment can affect them in a more positive way. So it really kind of comes to life for me. It's not just kind of looking at papers and looking at data. I can really talk to the patients and see the impact it has and really kind of connect the dots between the things that we're doing in our development program and then making a difference in their lives.

I can tell you that sometimes the changes we see are incredibly striking. We actually have an example of a young child with TK2 deficiency who was ventilator dependent and couldn't walk when she started the treatment. She was treated with a combination of pyrimidine nucleotides so these are two of the building blocks of DNA. And about a year and a half later, we have a video of her walking in indoor gym completely off the ventilator, so it's very striking there. So that's very gratifying; I think anyone can appreciate that. Sometimes the changes are not as obvious but still really very meaningful for patients. I'm thinking of an adult patient with TK2 deficiency who credits her treatment with allowing her to continue to work. She's actually a physician. So here's an example of where a drug is allowing her to do her work and what she does is to take care of other people. I actually find that really inspirational in terms of the challenges that she kind of overcomes and her dedication to her work. So those are just kind of two examples in the day-to-day kind of course of my job that I can appreciate the impact of the drug that we're developing it has on patients.

And I will say one other thing just in thinking more broadly about how we develop drugs is I think we have to get better at understanding rare diseases because there are so many of them. It's not any one disease may have perhaps a thousand of people, 2,000 people, but when you add that up if you look across all the rare diseases it's a lot of people. I think it's estimated there's over 7,000 rare diseases, and if you look in the US alone and you add up who's affected

by those rare diseases is probably about over 30 million people. So in essence, rare diseases aren't all that rare.

And I also do think the approaches that we developed for rare diseases, because they have few patients that we can enroll in trials, kind of challenge us to make us better at developing drugs in general. As an industry, it doesn't make sense for us to spend many years and a lot of time developing a drug if we can do it in less time and with fewer patients. So maybe trials don't have to be as large and a common disease maybe can be looked at and tested with newer approaches in a more efficient way. We can look at specific subsets more efficiently or we can understand complex situations more efficiently.

And so one of my thoughts is that looking at rare diseases and developing ways to think about how to do trials and how to develop drugs for rare diseases really will translate ultimately into overall how we develop drugs better overall for all sorts of diseases.

Taren: I love that thinking. And, again, going back to your proficiency as a scientific problem solver, that fits right in there. So where are some of those efficiencies you think that are being taken advantage of in the rare diseases and how it would translate to some of the larger clinical trials that are necessary for some of the more common diseases or diseases that have larger patient subsets to them. What are some examples? Do you have some?

Dr. Quan: Typically, in rare diseases, there are very few patients in order to enroll in trials. So every single patient that you look at, you have to think about and think about what is their disease, how do you think about the disease, what are they telling you; if you treat them, how do they respond and what does that tell you. And so, oftentimes, in very common diseases you're looking at patients in the aggregate, and I think what looking at rare diseases forces you to do is look at each one individually and then you have to think about how you develop somewhat standardized ways to look at that whether it's endpoints, thinking about how to do trials with very few patients and how to be really kind of efficient at squeezing all the information you can out of them, how to minimize their ability in terms of the things that you're measuring. All of those things I think really come to the fore when we're thinking about you know, how to do trials in rare diseases. The types of challenges are kind of similar but I think it's kind of it's not feasible to do something large so you have to do something smaller. Whereas in a more common disease, the typical approach in order to reduce variability is we'll study more people. And that typical avenue then is not open to you looking at rare disease so it kind of forces you into a space where you really have to face that challenge.

Taren: Absolutely. Great point. As a doctor, your clinical training gives you really a different kind of perspective into the drug development approach because you're looking at it from a different perspective. How has that medical training really influenced how you look at drug development?

Dr. Quan: I think actually that my clinical training really like as a foundation of how I approach drug development because thinking about the patient is ultimately the goal of developing the drug. So it can be for instance how do we assess the patient, how do we know what their

disease is like, how do we measure it, how do we know what effect the drug has had on them, how do we think about risk, what type of safety issues may come up for a patient who's taking this particular drug, and how do we think about the balance of benefit and risk. If someone is undertaking the risk, we want to make sure that the benefit is sufficiently large. And it really all comes down to thinking about how we've affected the patient really whether in a good or a bad way. In thinking about a patient, if I'm looking at data for instance, it may come across as tables and graphs and showing what a patient might have done on a particular endpoint.

For example, one common endpoint that is used is something called a six-minute walk, so this is how far our subject can walk in six minutes on a standardized layout. It's actually used fairly widely. It was initially used in looking at cardiorespiratory diseases and then has kind of migrated to be using in many different areas including like rare neuromuscular diseases like TK2. And so when I look at some of these numbers, it's all pretty dry, it's looking at numbers on a page or on the graph, but what I try to do is look across different pieces of information and see if they tell a story. So if someone's six-minute walk improved and maybe we have some other indicators, perhaps if their muscle function improved, perhaps something about their upper limb function improved or their respiratory function improved, then if I put all that together then it tells me maybe they had an overall improvement in their disease and what I'm seeing is an overall improvement on how their muscles are functioning.

So it's really kind of trying to reconstruct and have in my mind kind of the picture of the patient. Sometimes things go in different directions and I'm kind of scratching my head trying to figure out how to put that together. And so it's really thinking about how to understand a patient kind of when they are broken down and kind of putting it back together again. And I think my training as an internist kind of helps me think about how to diagnose and treat diseases and how to think about symptoms and figure out what's wrong and what to do. And then also my training in pulmonary and ICU medicine has presented me with a background in thinking of all sorts of different diseases, and diseases some of which are very acute and very severe forms of disease. So I actually find that the breadth of my clinical training and just really that outlook really underlies really all the thinking that I do about drugs on developing.

Taren: That's wonderful. And I love how you use that data to paint a picture of the patient rather than just as disparate data points.

Dr. Quan: Yeah. Otherwise, I find it difficult to keep that on mind, right? I mean, otherwise it's a number of sort of seemingly not related data points and that becomes hard to think about. So it's easier to kind of put it together.

Taren: Fantastic. Now, what are some of the trends that you're tracking right now in terms of the disease states that you're looking at and in general in the rare disease space?

Dr. Quan: Actually, there's a couple of things and I think this is probably kind of broader even than just the rare disease. I mean, I think scientifically there's a lot of more interest I think in the mitochondrial disease area recently and I think that's great. It's been an area that's very underserved in terms of even diagnosis and drug development. Kind of broadly, scientifically,

there's been a tremendous amount of energy and interest in cell and gene therapies and they've made huge advances over the past two years and the pace of advances is really striking there. I mean, there are cell therapies, things like Kymriah for instance to treat certain B-cell cancers, and that's where the patient's blood cells are taken out, they're genetically modified to attack their own cancer cells and then put back into the patient.

We have gene therapies, things like Zolgensma which has been developed to treat spinal muscular atrophy which causes a very severe form of muscle weakness. And children may never be able to sit independently so they have such severe muscle weakness, they don't have the strength in their truncal muscles to sit. In this kind of gene therapy, a virus is modified to contain the normal gene and then is injected into the body to replace the defective gene.

I mean, these are really pretty striking advances. A lot of scientific breakthroughs and clinical breakthroughs have come together to make these therapies possible and there are more and more therapies that are coming out for many diseases, rare and some more common diseases. And that's actually really very striking in this area over the past few years. It's really the pace of the advances that is striking there.

Taren: I agree. Terribly exciting science. But is the science moving too fast? I mean, can the industry, can physicians keep up with it?

Dr. Quan: That's a good question actually. It's only when you challenge things that you kind of force the field to figure out what to do with it, right? There are certainly some ethical issues that need to be dealt with, with CRISPR and editing genes for instance. It's really when you only have the potential to do something like this, that you challenge people in the field to figure out should you do this, how do you do this. You're probably aware that even with the cell and gene therapies, there's a lot of things in the press about reimbursement; how does that work? Well, it's really only when you have therapies like this, that you challenge people to think about their current models and how that either works or doesn't work, right?

So that's sort of exciting to see. These are really kind of game-changing therapies. They're really on the edge and they're not incremental therapies. Incremental things kind of fit within the current model, a better sort of a ME2, so a better version of the last kind of version 2.0 or 3.0 where you're sort of making an incremental improvement and people kind of know how to deal with it. What we're really talking about with these new therapies is they are really game-changing therapies and they cause people to think differently about how do you think about patients, is this going to last, is this going to be a cure, does someone need to be retreated. So it really does cause people to think differently about the whole environment in which the care is delivered. And I think that's actually really exciting.

So to the degree that people aren't necessarily ready for it, there is an element of that. It's a challenge to everyone to get ready for it, I suppose, is one way to think about it.

Taren: I like that everybody get ready for it, because it's coming; there's no going back now. We've seen...

Dr. Quan: Exactly, yeah.

Taren: So we have to be a little fearless to go forward. It's not the same...

Dr. Quan: That's right. It can feel sort of uncomfortable but I think you kind of have to deal with the fact that it is here. And I think that can be both scary and really a huge opportunity as well.

Taren: Absolutely. And I think that's part of it is you have to be comfortable with being uncomfortable if we're going to move forward. It's a great point. Speaking of being fearless, you've led multiple collaborations toward multiple IND/CTA submissions. In your opinion, what has made these partnerships so successful in moving these drugs through the pipeline?

Dr. Quan: Well, I think it's the mix of people having the right skill sets really from a technical perspective, as well as having good communication and the ability to work together. Now that I think about it, it's often not necessarily experience. I'm thinking of a couple examples. The first one being the first company I was at in Seattle, we work to file the NDA or the new drug application, and there were a handful of key people including me who had not done this before and I was new to the industry. In that case, it was a mix of the people and the challenge that will pull the team together. And in retrospect, I think some of us wondered whether we would have been so successful had we known like what we're up against when we signed up to do. I think in that instance, the goal was big but it was not too big, and it was just kind of like enough of a stretch; and everyone, it turned out, worked well together and communicated well. People covered for each other and we're able to pick up things that another person didn't feel as comfortable with.

Another example where a team I led, who had not worked together, achieved a big goal was when I was part of a larger company going through a restructuring. And this was in California, people get something called a WARN letter. And so people are sort of technically laid off and we're waiting to see who's going to be selected for the new organization. There was a lot of upheaval in the company and I remember we were kind of on the verge of starting up a particular study which it was going to be a proof of concept, meaning that this was a novel approach, it was a novel pathway, it was a novel drug, and we were testing it in an inflammatory disease. I remember actually going to a team meeting and saying, "I'm not really sure what we're supposed to do here. I got this letter, I'm sure many of you got this letter as well." And it was actually pretty interesting because in the course of that meeting everyone pretty much decided that we should continue doing what we're doing. We had been given the budget and there was a certain kind of timeline to getting the study started. Everyone felt that there was really a lot of value in working on this; everyone could see that this could have a big impact on patients; and everyone decided like, "Okay, let's just go for it." And I do remember one person saying, "I really don't know what's going to happen with the company or my job, but this is important and this is what I'm going to focus on in the short term."

And so that was actually really, really striking to me. These were people who didn't actually technically know that they had a job and yet they were actually incredibly motivated. And that

really taught me that it's not having the job that motivates people, but it's really kind of what the job means and what the job enables and how you express yourself, express motivation within the job. It's interesting when you ask this question, the two examples that I've given you are situations where the team didn't have the experience. I really wonder because they didn't have the experience, perhaps they were more open to listening to each other, more open to just thinking about how can we make this work. And sometimes when you have people who kind of have a certain expectation, they may think, "Okay, this is the way it's going to work" and maybe that's not everyone's expectation.

So I think that there's sort of combination of having people who are really motivated and committed, people who have the right background to bring to the table, and really having really good communication and common expectations.

Taren: I think that's a really interesting perspective because you're right, those who have been down that path before are not always open to new ideas because it's always been done this way. But folks who haven't done it, there are no guidereils.

Dr. Quan: Right. And sometimes it's not even conscious, it's not even said. There are many expectations that we bring that we don't necessarily kind of say, "Well, this is what I expect" because you think everyone would expect that. So I think there's a combination and what it tells me is that someone who's like already done the job, maybe that's actually not the best person that you choose for the team because maybe they don't bring the openness and the energy to the project that someone who's really kind of looking for a challenge and looking to prove themselves and show something.

Taren: Yeah, that's great. Speaking of that, what are some of those other things you look for in team members when you're looking to build out that team?

Dr. Quan: Well, I think passion and commitment are really important and with that comes a dedication to doing whatever it takes to move things forward. For instance, at Modis, which was a small company, we started working on the treatment for thymidine kinase 2 deficiency. Zogenix also had an ongoing program using a novel approach to treat rare treatment-resistant epilepsies including Dravet syndrome and Lennox-Gastaut syndrome. And when Modis was acquired Zogenix, we could all see that we have this commonality and commitment to patients with really large unmet needs. And in fact, that that's been a good fit; and in fact, Zogenix's mission really is to develop transformative therapies for rare diseases. So that kind of passion and commitment I think is really important. I think also the ability to look at problems in different ways. People with different training and different backgrounds will naturally look at problems in different ways, but then it's also important to be open to being challenged about what your way of thinking is.

And then the ability to kind of accept that challenge to be able to disagree about an issue and kind of hash it out, discuss it, come out with a solution that no one person individually could have figured out, but really a group of people figured it out. And so I think that's really the fun

part of being part of a team is that no one person has the answer, but it's kind of the team that figures out the answer and it's really better than the sum of its parts.

Taren: I love that way of thinking. When you're trying to manage those teams and especially in drug development which is fraught with sometimes not good news just because of the nature of the beast. How do you keep your teams motivated and optimistic?

Dr. Quan: Well, I think part of it is sort of understanding people's commitment to it and making sure that people understand this is what we're doing, here's the disease that we're trying to make better, here's the patient. Oftentimes, patients can really express that really well and they can express 'here are the challenges that I see every day, here are the things that maybe you don't have a problem doing but are incredibly challenging for me, and here's what I can do if I overcome this part of the challenge.' So I think part of it is making sure that people understand what the end goal is. And then also, as you hit bumps along the road, trying to remain optimistic and kind of remaining creative kind of in that sentence and say, "Okay, well, this is a bump in the road. Let's figure out what we can do to kind of overcome this" and kind of providing some framing and some targets for 'okay, well, let's make sure that we understand this.' If there was a safety issue – well, let's understand. Was there something specific about the patient that actually predisposed them to this – let's understand everything we can. Was there something about the drug or the pathway; and trying to kind of blend that scientific understanding, that clinical understanding, and also just, 'okay, where does this put us?' Is this something that means that the drug is not safe and we should stop because we don't want to hurt anyone, or was this something unusual that happened because this particular patient had an unusual predisposition to it. So it's really helping to focus people and kind of leverage their backgrounds and helping navigate out of that.

Taren: Wonderful. Thank you so much. That's great insights. To switch tacks just a bit, unfortunately, today, there still aren't a ton of women sitting in chief medical officer roles. As such, you really are a role model to other women especially in the scientific field. What does that mean to you?

Dr. Quan: It's interesting. I don't really necessarily think about that all the time, but I think in thinking about kind of this particular podcast and thinking about that, any woman I think juggles a lot of different roles, right? There's our work role, there's kind of our home role, and then often if you have kids there's kind of being a parent. And I think part of it is just kind of making it all work and showing people that it can be done. The flow of each of these roles is very different and I think there has to be an intentionality to make it work and also to really want to make it work. I know for instance when I had kids, I took 12 weeks maternity leave and I really enjoyed that time with them. Taking care of newborns, it's very different than going back to the office. And I will tell you because when you're taking care of kids, it doesn't end. It kind of goes on and on, and it's really about being there, right? Whereas I can tell you that it was somewhat refreshing when I went back to the office to realize that something had a beginning, a middle, and an end and I could finish something. So I realized that there are different things that each of these roles are important for me. And it was important for me to figure out a way to make it all work because I wanted to experience all of those.

It is a bit of a challenge. I think women have more challenges because from a societal perspective, there's the expectation that women take a greater role in terms of parenting and things at the home. I hope that that's changing with all of the discussion about diversity these days, but I think that that's where we are right now. And I think part of what this is, is so that it can be done, to think very carefully about what it is that I want to get out of each of these roles, and to be very intentional to try to optimize that.

Taren: Fantastic. We would hope that with so much focus on diversity and inclusion and equity that we would see the change. But I think we're looking at reports coming out from COVID that we're seeing more and more women who are opting to step back right now on their careers because it's just too much to manage all – working remotely, managing children remotely, all of that. And there's a fear that this could really set women back quite a bit. So, hopefully, companies are going to be stepping up and supporting their female executives in ways that they haven't had to before.

Dr. Quan: Yeah, I agree. I think in the best of times without a pandemic, it's always sort of a balance, it's juggling, right? And then in the pandemic time, it's even more juggling and I think what we're seeing there is the fact that things were kind of difficult to juggle as it was and then you have a pandemic and you have kids at home or other roles that come into play and it's impossible to juggle that. I really do hope that with the new kind of broader thinking about this, that ways can be found to support women as they go through this. And it's really not just about supporting women, it's about supporting families and supporting men as well; that people think more broadly about this and recognize that women and a lot of other people and just thinking about diversity in different voices have a lot to add to the work environment and to the pharmaceutical industry in particular, and it's a loss if there is not the support provided to enable that to happen.

Taren: Absolutely. Such an important point, Dr. Quan; it isn't just about women, it's about the family unit, it's about men as allies, it's about the whole thing – exactly. So thank you so much for that clarification. You've had a very successful career; is there anything that you know now that you wish you had known as you were moving up the ranks? What piece of advice would you give to your younger self?

Dr. Quan: I've always thought of myself as kind of a scientist and a physician and I tend to look at facts. What some of my experiences have really taught me is looking at the team, the environment, kind of even equally is important. And I think that's something that I wish that I could have more fully appreciated; that it's not just for instance here is the disease I'm developing a drug for, but who exactly is on the team? Who can I learn from there? I think if I had appreciated more of that, how important that is, I think that would have been helpful to me.

Taren: I think that's a great insight. Thank you so much for sharing that. And finally, because this is our WoW podcast program, is there an accomplishment or a moment in your career that either changed the trajectory of your career or has left you with a lasting impression?

Dr. Quan: We touched about this early on when you asked me kind of about my career trajectory and how I ended up kind of where I was. And it was really, I think, in terms of that leap of faith going from the academic setting to industry. Even though it was scary at the time, I do feel that I made the right call. It really opened up an industry that I'd never thought of previously. And having been in industry for a number of years at this point, physicians have a very broad training that can be applied in so many different ways, there's such a range of choices in terms of the type of company, the size of company, different approaches and technologies, whether you do things that what we'd consider early development which transitions concepts from the bench into the clinic or late development which are larger trials to confirm safety and efficacy of the drug, or whether you are involved more on the clinical side or the business side – there's just a huge number of opportunities there. And I had never realized that there was that many choices there when I kind of made that leap.

As I think about this, you can evaluate your choices, at some point you take a calculated risk. You have to trust yourself that you'll figure it out as you go. I think it was the right choice for me even though it was pretty scary at certain points. I think for other people, I would say trust yourself, take a leap, you'll figure it out as you go.

Taren: Fantastic. Thank you so much. And we're so glad you took that leap because you're doing such remarkable things in a disease that really needs that focus and attention. So congratulations to you on all your success and we wish you continued success in the future. Thank you so much for being part of our WoW podcast program.

Dr. Quan: Thanks very much, Taren. I really appreciate the opportunity to talk to you and to share some thoughts from my career.

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